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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/724,416	JIN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,51-53,56-58,61-63,66-71,73,74,76-78 and 80-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,51-53,56-58,61-63,66-71,73,74,76-78 and 80-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 49, 51-53, 56-58, 61-63, 66-71, 73, 74, 76-78, and 80-83 are pending and under consideration in the application.

2. In the prior action, the Final action mailed on July 10, 2007, claims 49, 51-53, 56-58, 61-63, 66-74, 76-78, and 80-83 were pending and rejected.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 8, 2007 has been entered.

In this submission, claims 49, 57, 58, 73, 74, and 76 were amended, and claim 72 was cancelled.

The amendment to the claims cancels the subject matter elected in the Response of November 10, 2005, and limits the pending claims to a previously non-elected invention.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on August 8, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

5. **(New Objection- Necessitated by Amendment)** Claims 51-52, 56, 61-63, 66-68, 76-78, and 80-82 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of these claims depends from a claim describing a recombinant attenuated RSV comprising a genetic alteration or modification, wherein the alteration or modification is a deletion of the NS1 gene. The indicated dependent claims purport to further identify the genetic alteration or modification as being "in a regulatory domain," "in a functional domain," or as "a deletion of one of more nucleotides." In each case, these claims appear to read on embodiments wherein the alteration or modification may be a modification involving less than the entire gene. However, as the independent claims have already defined the alteration or modification as being a deletion of the entire NS1 gene, these dependent claims appear to read on embodiments not included in the claim from which they depend.

6. **(New Objection**) Claims 53, 69, and 83 are objected to because of the following informalities: it is suggested that the language "to go through only one round of replication" be replaced with the language - - of going through only one round of replication- -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Withdrawn)** Claims 49, 51-53, 56, 70, 71, and 73, 74, 76-83 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain recombinant attenuated RSV viruses as vaccines, does not reasonably provide enabling support for the use of any of the claimed viruses as anti-RSV vaccines. In view of the amendment of the claims, the rejection is withdrawn.

9. **(Prior Rejection- Maintained)** Claims 49, 51-53, 56-58, 61-63, 66-74, 76-78, and 80-83 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the claimed RSVs wherein the viral genomes comprise any deletion. In view of the amendments to the claims, the rejection is withdrawn.

10. **(Prior Rejection- Maintained)** Claims 49, 51-53, 55-58, 60-63, 65-83 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected as lacking sufficient written description support for the claimed general of viruses comprising any recombinant RSV comprising any deletion resulting in an attenuated virus. Claim 72 has been cancelled. The rejection is therefore withdrawn from this claims. Independent claims 49, 57, 58, 73, and 74 have been amended to require the deletion of the entire NS1 gene. The rejection is therefore withdrawn from these claims, and the majority of the dependent claims.

However, dependent claims 56, 61, 66, 70, 76, and 80 are each drawn to embodiments wherein the RSV may lack only "one or more nucleotides." As was indicated above, these claims

are not properly dependent on the independent claims. Thus, for the present rejection, the claims are treated as independent claims.

As each of the these claims read on RSVs in which the genetic modification may be only a single nucleotide deletion, and as the application provides no examples of any deletion other than the deletion of the full NS1 open reading frame, and as it is not clear from the application what regions of the NS1 protein are required for its activity such that those in the art would be capable of making deletions in this gene with the desired attenuate phenotype, the rejection is maintained over these claims for the reasons above, and the reasons of record.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. **(New Rejection)** Claims 49, 51, 52, 56-58, 61-63, 66-68, 70, 73, 74, 76-78, and 80-82 are rejected under 35 U.S.C. 102(e) as being anticipated by Murphy et al. (U.S. Patent 5,993,824- of record in the action mailed on June 5, 2002). These claims read on a composition comprising a recombinant attenuated RSV comprising a deletion of the NS1 gene. It is noted that support for this specific embodiment is not found in the parent application 08/316,439.

The teachings of the Murphy reference have been described in part previously. See e.g., Office actions of February 7, 2006 (pages 16-17), and June 5, 2002 (page 6). As was previously indicated, this patent teaches recombinant attenuated RSV, and compositions comprising such. In addition, the reference specifically teaches an RSV comprising a deletion of the NS1 gene. See e.g., columns 112-113, and col. 6. Because the reference teaches the gene deletion, it inherently meets the limitations of claims 56, 61, 66, 76, and 80. Moreover, as the reference teaches the deletion of both functional and regulatory regions of the gene, it also anticipates claims 51, 52, 62, 63, 67, 68, 77, 78, 81,and 82. Moreover, it is noted that the reference indicates that an RSV having the deletion produces smaller plaques, indicating that the RSV mutant is attenuated. See e.g., col. 113, lines 45-55.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. **(New Rejection)** Claims 49, 51-53, 56-58, 61-63, 66-71, 73, 74, 76-78, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy as applied to claims 49, 51, 52, 56-58, 61-63, 66-68, 70, 73, 74, 76-78, and 80-82 above, and further in view of the teachings of Knipe et al. (U.S. 7,223,411) and Inglis et al. (U.S. 5,665,362). The previously rejected claims have been described above. Claims 53, 69, 71, and 83 are directed to embodiments of the claimed invention wherein the viruses are indicated to be capable of going through only a single round of replication. The application teaches (on page 30) that this is accomplished through the deletion of an essential gene for such replication.

As indicated above, Murphy teaches a NS1 deficient RSV, and indicates that it may be used as an anti-RSV vaccine by identifying it as an attenuated virus. The reference also suggests providing additional modifications to the virus, including ones that restrict the ability of the virus to replicate (column 22, lines 34-41). Further, the reference also identifies the N, P, and L proteins as essential for viral replication. However, the reference does not teach or suggest the modification of the virus such that it meets the present claim limitations.

Other teachings in the art do indicate that it was known in the art to render viruses to be used for vaccine purposes replication defective by the deletion of one or more of the genes required for viral replication. See e.g., Knipe, abstract and columns 1-2; and Inglis, columns 1-2. From these teachings, it would have been obvious to those of ordinary skill in the art to make such a modification to the viruses of Murphy through the deletion of one or more of the N, P, or L proteins from the RSV genome. The combined teachings of these references therefore render the claimed invention obvious.

15. **(Prior Rejection- Withdrawn)** Claim 72 was rejected under 35 U.S.C. 103(a) as being obvious over Murphy et al., U.S. Patent 5,993,824 (of record in the action mailed on June 5, 2002). In view of the cancellation of the elected embodiment of this claim, the rejection is withdrawn.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

17. (New Rejection) A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

18. **(New Rejection)** Claim 49 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 24 of copending Application No. 11/690,957. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

19. **(New Warning)** Applicant is advised that should claims 57 and 61-63 be found allowable, claims 58 and 66-68 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Similarly, should claims 73 and 76-78 be found allowable, claims 74 and 80-82 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the present case, as both the genetic alterations of claims 57, 61-63, 73, and 76-78 have been defined by the claims as being the same as the modifications of claims 58, 66-68, 74, and 80-82, each of these two sets of claims each represents a substantial duplicate of the other set of claims.

20. **New Warning)** Applicant is advised that should claim 53 be found allowable, claim 71 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). While claim 71 depends (indirectly) from both claims 57 and 58, the claimed vaccine composition of claim 71

would encompass identical subject matter to claim 53 regardless of which of these alternative claims is chosen. See, the warning immediately above.

21. **(New Warning)** Applicant is advised that should claims 49, 57, 58, 73, and/or 74 be found allowable, claims 53, 61, 66, 76, and/or 80, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).The deletion of the entire NS1 gene is inherently a deletion of one or more nucleotides. Thus, claims 53, 61, 66, 76, and 80, which read on the RSVs of claims 49, 57, 58, 73, and 74 respectively, read on the same subject matter as their respective dependent claims.

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. **(New Rejection)** Claims 51, 52, 56, 57, 58, 61-63, 66-68, 70, 73, 74, 76-78, and 80-82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of copending Application No. 11/690,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims read on species of the presently claimed inventions, and would anticipate the present claims if applied as prior art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. **(New Rejection)** Claims 53, 69, 71, and 83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of copending Application No. 11/690,957 in view of Murphy (supra), Knipe (supra.), and Inglis (supra). The copending claims do not teach or suggest the modification of the virus such that they are capable of going through only a single round of replication. However, as was described above, the teachings of the three additional references render obvious the making of such modifications to RSV viruses to be used as vaccines. The combined teachings of these references therefore render the claimed inventions obvious.

This is a provisional obviousness-type double patenting rejection.

25. **(Prior Rejection- Withdrawn)** Claims 49, 51-53, 55-58, 60-63, 65-83 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 10, 12, 21, and 22 of copending Application No. 09/724,388. In view of the abandonment of the copending application, this rejection is withdrawn.

26. **(Prior Rejection- Withdrawn)** Claims 49, 52, 55-58, 60, 61, 63, 65, 66, 68, 70, 72, 73-76, 78-80, and 82 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 36, 37, 39, and 41-43 of copending Application No. 10/975,060. In view of the amendment of the present claims, the rejection is withdrawn.

27. **(Prior Rejection- Withdrawn)** Claims 49, 52, 56-58, 61, 63, 66, 68, 70, 72, 73, 74, 76, 77, 78, 80, and 82 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/078,900. In view of the amendment of the present claims, the rejection is withdrawn.

Conclusion

28. No claims are allowed.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. Lucas/
Patent Examiner, AU 1648